

*ART 34 AMOT*

A DEVICE FOR INJECTING AN INTRAOCULAR LENS MADE OF FLEXIBLE MATERIAL

5        The present invention relates to a device for use after the natural lens has been removed to inject an intraocular lens (IOL) made of flexible material that has previously been deformed by being compressed, rolled up, or folded.

10      *Inst 2* Most presently known intraocular lens injectors comprise a cylindrical body in which a piston is slidably or screwably mounted: the body is designed to receive a cartridge having a cylindrical endpiece, a loading chamber for receiving the lens to be injected, and a hinged fin; the lens is placed in the chamber and the fin is folded down to close the chamber, thereby deforming 15 the lens, after which the cartridge is placed in the body; once the surgeon has engaged the endpiece in the incision in the eye of a patient, the lens can be injected directly into the capsular bag of the eye being operated on by acting on the piston. Once released, the 20 lens returns to its initial shape.

25      Other injectors are also known comprising a loading chamber provided with access openings that can be closed by a flap, by a slide, or by being mounted on the endpiece. The lens is deformed either by closing the flap or the slide, or by direct thrust from the piston.

30      In all those cases, the piston propels the lens into a space of section that tapers progressively, thus contributing to deforming the lens until it reaches the minimum internal section of the endpiece.

35      Document WO 96/13229 discloses a two-part device comprising forceps and a tubular element each of which needs to be held in one hand. The user takes hold of the lens with the forceps and inserts it into a loading chamber of the tubular element.

35      The present invention provides an injector which does not have a chamber or loading system with direct access (such as a cartridge, flap, slide, removable

1a

endpiece, ...), and in which the lens is deformed solely by direct thrust from the piston.

The injector of the invention is characterized by a one-piece syringe body having a cylindrical first portion of approximately semicircular section capable of

containing an undefomed lens, an injection endpiece, and an intermediate portion connecting these two portions together and of section that tapers progressively from the cylindrical first portion to the endpiece. The 5 section of the endpiece, which can be circular, oval, or flattened, has dimensions that are adapted to the size of incisions used in the surgical technique of phacoemulsification (presently 3.2 millimeters (mm) or even less as the technique evolves).

10 In a preferred embodiment of the invention, the injection end of the piston has a plurality of fingers capable of flexing towards one another as the piston moves while simultaneously pushing the lens into the endpiece. By means of this disposition, thrust on the 15 lens is exerted at a plurality of points, thereby stabilizing its orientation. The piston is made as a single piece of hard plastics material, and the fingers are caused to be flexible merely by their shape.

20 Still in a preferred embodiment of the invention, the lens is delivered in place in the injector, thus relieving the surgeon of the need to load the lens, and constituting a sterile assembly ready for use. Depending on the method of sterilization used, the lens can 25 optionally be packaged dry or immersed in a liquid inside the syringe body: when in a liquid, the assembly is fitted with sealing gaskets for the piston, and with a stopper fitted to the endpiece.

30 Various embodiments of the injector of the invention are described below as non-limiting examples and with reference to the accompanying drawings, in which:

- Figure 1 is a perspective view of the injector body;
- Figure 2 is a perspective view of the injector piston, with an undefomed lens ready for injection;
- 35 • Figure 3 is a perspective view showing the piston mounted in the syringe body, with the lens undefomed, ready for injection;

- Figures 4A to 4E are section views of the body on planes A-A, B-B, C-C, D-D, and E-E at the moment when the lens passes through said planes;
- Figures 5A to 5E are section views of the body on the planes A-A, B-B, C-C, D-D, and E-E at the moments when the ends of the piston pass through said planes;
- Figures 6A to 6E are views similar to Figures 5A to 5E in a second embodiment;
- Figures 7A to 7E are views similar to Figures 5A to 5E in a third embodiment;
- Figures 8A to 8E are views similar to Figures 5A to 5E in a fourth embodiment;
- Figures 9A and 9B are views similar to Figures 2 and 3 with the lens being shown during injection, partially engaged inside the endpiece;
- Figures 10A and 10B are views similar to Figures 2 and 3 with the lens being injected, and partially free at the end of the endpiece;
- Figures 11A and 11B show the same elements and at the same stage as in Figures 10A and 10B, but with the injector turned over so that its chamfer faces downwards; and
- Figure 12 is a perspective view of the piston on its own in a second, undefomed embodiment prior to being mounted in the syringe body. *(11385)*

As shown in the figures, the lens injector of the invention comprises a one-piece syringe body and a piston which are given respective overall references 1 and 2 in the drawings.

The body 1 comprises a portion 3 of semicircular section with a curved face 3a and a plane face 3b, its maximum internal width being substantially equal to that of an intraocular lens 4 when flat (Figure 4A). This portion 3 is followed by a conical portion 5 which connects progressively with a portion 6 that is practically cylindrical. The portion 5 has a curved face 5a and a trapezoidal plane face 5b. The inside diameters

of the portion 6 are such that the lens 4, when folded over, can be received therein, i.e. about 1.6 mm x 2.3 mm (Figure 4E). The portion 6 is terminated by an injection endpiece 7 whose ends can be straight or chamfered and whose outside diameters are about 1.9 mm x 2.6 mm. Depending on the preferred opening direction for the lens, a chamfer, if any, can be oriented towards the curved face side, as in the drawings, or towards the opposite side.

In the embodiment of Figures 1 to 3 and 9 to 12, the piston 2 has a cruciform portion 8 terminated by a cylindrical guide head 9 which can include sealing gaskets and which is of a diameter such as to enable it to travel freely in the portion 3 of the body 1 while guiding the piston. Beyond the head 9, the piston has a multifinger zone which, in the example shown, comprises a central finger 10a and two side fingers 10b. The central finger 10a is extended by a spatula 10a preventing the lens from deforming towards the plane face 3b of the body.

In order to use the injector, the lens is placed in the portion 3 of the body 1 and the piston is mounted in the body until the position shown in Figures 3, 4A, and 5A is reached. The assembly can be sterilized or assembled in sterile manner and is delivered to the surgeon in this form, the surgeon can then remove any stopper and place some lubricating viscoelastic solution in the conical portion 5 of the body 1 for the purpose of improving injection of the lens, should that be part of the surgeon's personal technique.

Using the injector prepared in this way, the surgeon pushes against the piston 2 so the lens 4 is moved into the conical zone 5 of the body: the lens is thus compressed between two diametrically opposite points, thereby causing it to buckle towards the curved face 5a of the body 1 (Figure 4B), since the other face 3b-5b is plane and initially pressed against the lens (Figure 4A),

thus preventing it from buckling in the opposite direction. Thereafter, the lens comes into contact with the curved face 5a so its thinner free edges begin to fold in under towards the plane face 5b (Figure 4C).

5 Simultaneously, the side fingers 10b move towards each other (Figures 4C and then 5C). As the section of the portion 5 tapers, the free edges of the lens 4 slide over the plane face 5b (Figure 4D). The central portion of the lens 4 remains constantly pressed against the curved 10 face 5a, and is therefore stabilized while it is being pushed.

Once they have gone through the conical portion 5 of the body 1, the fingers 10a and 10b meet to constitute a cylinder that occupies practically the entire section of the end 6 of the body 1 (Figure 5E). Meanwhile, the lens 15 4 is rolled up and likewise occupies this section in full (Figure 4E). When the lens is about to come out, the surgeon inserts the end 7 into the incision with the chamfer facing downwards. Then by continuing to press 20 against the piston 2, the surgeon progressively injects the lens into the eye of the patient, engaging it in the capsular bag. Because the lens is resilient, it unfolds and returns to its initial shape.

Once the piston has been pushed fully home, the 25 three fingers project slightly from the end of the body 1 so as to ensure that the lens is released in full.

The embodiment of Figures 6A to 6E is similar to that described above: it differs solely by the fact that the central finger 10a presses continuously against the 30 curved portions 3a and 5a of the body of the injector.

In the embodiment of Figures 7A to 7E, which is similar to the preceding embodiment, the separation planes between the fingers 10a and the fingers 10b instead of being perpendicularly to the plane face of the 35 body, are inclined relative thereto.

In the embodiment of Figures 8A to 8E, the central finger 10a is wedge-shaped. As the side fingers 10b move

towards each other in the conical portion 5, they push the central finger 10a by a wedging action towards the curved face 5a, thus following the movement of the lens.

Naturally, the present invention should not be considered as being limited to the embodiment described and shown, but on the contrary covers all variants thereof.